

still quoting the JAMA, the Editorial continues "Many B-Complex preparations available to the physician and public today are definitely unbalanced either too much thiamine or not enough riboflavin, niacin, or pyridoxine" were false and misleading since the quotations did not appear in an editorial in the September 1, 1945, issue of the Journal of the American Medical Association and since the article did not contain B vitamins in balanced proportions. The article was misbranded in this respect when introduced into and while in interstate commerce.

The article was alleged also to be misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 4173.

DISPOSITION: August 14, 1953. Default decree of condemnation and destruction.

20699. Adulteration and misbranding of Raymor capsules. U. S. v. 4 Bottles, etc.

(F. D. C. No. 34879. Sample Nos. 33850-L, 66492-L to 66495-L, incl.)

LIBEL FILED: March 11, 1953, Eastern District of Michigan; amended libel filed March 23, 1953.

ALLEGED SHIPMENT: On or about November 1, 1951, December 3, 1952, and January 20 and 23, 1953, by the Raymor Food Products Co., from Chicago, Ill.

PRODUCT: 4 180-capsule bottles of Raymor No. 50 capsules, 50 50-capsule boxes and 11 100-capsule boxes of Raymor No. 9 capsules, 5 100-capsule bottles of Raymor No. 33 capsules, 11 60-capsule bottles of Raymor No. 44 capsules, and 20 90-capsule bottles of Raymor No. 47 capsules, at Jackson, Mich., together with a number of leaflets entitled "Professional Order Blank" and 1 copy each of 5 issues of a publication designated "Raymor Nutritional Review" distributed monthly by the Raymor Food Products Co. and dated March, May, June, November, and December, 1952.

LABEL, IN PART: "Raymor Number 50 180 Capsules 30 Day Supply Of A Dietary Supplement Composition—The recommended daily dosage of six capsules provides as follows: Ingredients * * * % M. D. R.—Vitamin C (Ascorbic Ac.) 210.0 Milligrams 433% * * * Iodine (KI) 0.45 Milligrams 450% * * * Calcium (Bone phosphate) 950.0 Milligrams 125% Phosphorus (Bone Phosphate) 565 Milligrams 75%. The Purpose Of This Product Is Nutritional";

"Raymor Number 9 50 No. 0 Size Capsules * * * each three capsules standardized to contain—Vitamin D (irrad. yeast) 400 U. S. P. Units Natural Bile Salts—Natural Bile Salts Pancreatin, Pepsin, Papain, Duodenum, for Enzyme activity; Pectin and Gel from Cranberry and edible Irish Moss seaweed; Alkaline Buffer from Lime salts; Calcium and Phosphorus from edible beef bone powder and the natural B-Complex from Liver substance, Wheat Germ Embryo and vegetable concentrates * * * 3 capsules of Raymor No. 9, when taken daily, will provide 400 U. S. P. units of Vitamin D (full daily minimum requirement). The Purpose Of This Product Is Nutritional";

"Raymor * * * Number 33 100 No. 0 size Capsules * * * each three capsules standardized to contain Vitamin C (ascorbic acid) 750 Mgs. (equal to 15,000 U. S. P. Units) 25 times the Min. Daily Requirement Plus Protein Factors and Chromo-Proteins From Liver, Red Bone Marrow, Spleen, Stomach and Pancreas Substances; Iodine from Kelp; Calcium and Phosphorus from edible cooked Beef Bone and Lime Salts; Hypoallergenic Soy Lecithin and dried powdered Orange Concentrate. There is no scientific data that glandular material contained herein is medically or therapeutically active. Directions

One Capsule three times daily or as directed by your doctor as a supplement to the diet. The Purpose Of This Product Is Nutritional";

"Raymor * * * Number 44 60 Capsules * * * Each three capsules contain Rutin 50.0 Mgs. Vitamin C (Ascorbic Ac.) 30.0 Mgs. Vitamin B₁ (thiamine) 1.5 Mgs. Niacinamide 45.0 Mgs. together with Magnesium Salts, Bile Salts, & B-Complex Vitamins from Liver Substance, Concentrated Yeast & Stabilized Germ of Wheat Three capsules contain 1½ times the minimum daily requirements of Vitamin B₁ and the full M. D. R. of Vitamin C Directions One capsule three times daily at mealtime or as directed by your doctor. The Purpose Of This Product Is Nutritional";

"Raymor Number 47 90 Capsules * * * Each six capsules standardized to contain % M. D. R.—Folic Acid 3.0 Milligrams Vitamin B₁₂ (Crystalline & Concentrate) 12.0 Micrograms Vitamin A (Natural Ester) 6,000.0 U. S. P. Units 150% Vitamin B₁ (Thiamine) 12.0 Milligrams 1200% Vitamin B₂ (Riboflavin) 5.0 Milligrams 300% Vitamin C (Ascorbic Acid) 60.0 Milligrams 200% Niacinamide (P. P. Factor) 90.0 Milligrams Ferrous Gluconate (110 mgs. elem. iron) 1,050.0 Milligrams 1100% Copper Peptonate 9.0 Milligrams 250% Manganese Hypophosphite 30.0 Milligrams Liver, Stomach & Hemoglobin (Desiccates) 900.0 Milligrams Amino Acid Salts 48.0 Milligrams. In a nutrient base containing copper chlorophyllin, red bone marrow substance, natural iodine from kelp and acid buffering mineral salts. * * * Directions Two capsules taken three times daily at mealtime, or as directed by your doctor as a supplement to the diet. * * * The Purpose Of This Product Is Nutritional."

NATURE OF CHARGE: Raymor No. 50 capsules. Adulteration, Section 402 (b) (1), valuable constituents, calcium phosphorus, and vitamin C, had been in part omitted or abstracted from the article. Misbranding, Section 403 (a), the statements in the labeling of the article, namely, "The recommended daily dosage of 6 capsules provides as follows: * * * Calcium * * * 950.0 Milligrams 125% M. D. R." and "Phosphorus * * * 565 Milligrams 75% M. D. R." were false and misleading since 6 capsules of the article provided less than 950 milligrams of calcium and less than 125 percent of the minimum daily requirement for calcium, and less than 565 milligrams of phosphorus and less than 75 percent of the minimum daily requirement for phosphorus; and the statements in the labeling of the article, namely, "The recommended daily dosage of 6 capsules provides as follows: * * * Vitamin C (Ascorbic Ac.) 210.0 milligrams 433% M. D. R." and "Raymor No. 50 * * * A Multi-vitamin * * * dietary supplement containing * * * 210.0 mgs. C * * * in the recommended daily dosage of 6 capsules" were false and misleading since 6 capsules of the article provided less than 210 milligrams of vitamin C (ascorbic acid) and less than 433 percent of the minimum daily requirement for vitamin C. Further misbranding, Section 403 (a), the labeling of the article consisting of the issues of the "Raymor Nutritional Review," mentioned above, was also false and misleading. Such labeling when taken as a whole, as well as in the specific statements and read in the light of the setting in which such labeling was intended to be read, conveyed to the public a meaning which represented and suggested that the article was effective for successful growth and maintenance of health; that it was effective, by reason of its content of choline and inositol, for arteriosclerosis; by reason of its content of vitamin B₁₂, for chronic dermatitis and chronic urticaria; by reason of its content of vitamin E, in the management of retrolental fibroplasia; for neurologic disturbances in diabetic sufferers; for psychogenic asthma; to prevent intravascular coagulation and nutritional breakdown; to

improve metabolism and cellular processes by replenishing all known deficiencies; to prevent and treat common chronic diseases—hypertension, diabetes, cancer, arthritis, degenerative diseases of the liver and kidneys, obesity, and cardiovascular-renal disease; arteriosclerosis, pain in rheumatoid arthritis, increased tendency for accidents caused by obesity, chronic physical and mental ill health, and congenital debility in infants; to accelerate wound healing and lessen the possibility of intercurrent infection; for “psychomatic” disorders of the heart, including irregularities of rhythm, unusual sensations about the heart such as oppression, tightening, pain, numbness, shortness of breath, feeling of faintness, weakness, and “all gone,” free perspiration and sinking sensation; to improve vision in senile muscular degeneration; by reason of its content of liver and vitamin B complex, to remedy diarrhea following use of antibiotics; by reason of its content of vitamins, minerals, and amino acids, to remedy lesions of the mouth; by reason of its content of liver, to remedy reproductive failure; to remedy nervous illness in elderly people; to prevent invalidism and senility in the aging, breaking down of older individuals and emotional stress and psychological changes in the aged, manifesting themselves in nervousness, depression, insomnia, and “a wide variety of somatic symptoms, difficulties in memory, irritability, insomnia, and a general feeling of apprehensiveness and restlessness”; to relieve elderly people from the stresses and strains of life produced through functional disturbances of nervous origin and anxiety as to organic illnesses; to exert a favorable influence upon the entire outlook of the consumer; to prolong the period of the consumer’s activity; by reason of its content of folic acid, for diarrhea and colitis; by reason of its vitamin B₁₂ content, for spastic paraplegia, spino-cerebral syndromes of the acromegaly type, cerebellar atrophy, and Korsakoff’s psychosis and early cases of polyneuritis when not associated with rheumatic disorders. The article was not effective for such purposes, and it was not capable of fulfilling the promises of benefit stated and implied. The Raymor No. 50 capsules were adulterated and misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

Raymor No. 9 capsules. Misbranding, Section 403 (j), the article purported to be and was represented as a food for special dietary use by reason of its vitamin and mineral content, and its label failed to bear, as required by the regulations, a statement of the amounts of the several vitamins of the vitamin B complex, and of calcium and phosphorus contained in the article, in the manner prescribed by the regulations.

Raymor No. 33 capsules. Misbranding, Section 403 (j), the article purported to be and was represented as a food for special dietary use by reason of its mineral content, and its label failed to bear, as required by the regulations, a statement of the amounts of iodine, calcium, and phosphorus contained in the article, in the manner prescribed by the regulations.

Raymor No. 44 capsules. Misbranding, Section 403 (j), the article purported to be and was represented as a food for special dietary use by reason of its vitamin content, and its label failed to bear, as required by the regulations, a statement of the amounts of the several vitamins of the vitamin B complex contained therein (other than vitamin B₁), in the manner prescribed by the regulations.

Raymor No. 47 capsules. Misbranding, Section 403 (a), the labeling of the article which contained statements representing and suggesting that 6 capsules of the article containing 9 milligrams of copper peptonate provided

250 percent of the minimum daily requirement for that substance was misleading since such statements created the impression that a minimum daily requirement for copper peptonate has been established, whereas a minimum daily requirement for copper peptonate has not been established; and, Section 403 (j), the article purported to be and was represented for special dietary use by reason of its vitamin and mineral content, and its label failed to bear, as required by the regulations, a statement of the amount of iodine contained in the article and the statement "The need for folic acid, vitamin B₁₂, and manganese hypophosphite in human nutrition has not been established," in the manner prescribed by the regulations.

Further misbranding, Section 403 (f), the information required by Section 403 (j) to appear on the label of the Raymor No. 9 capsules, No. 33 capsules, No. 44 capsules, and No. 47 capsules was not prominently placed thereon in such terms as to render such information likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The Raymor No. 9 capsules, No. 33 capsules, No. 44 capsules, and No. 47 capsules were misbranded in the above respects when introduced into and while in interstate commerce.

The Raymor No. 50 capsules were alleged also to be misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices, No. 4134.

DISPOSITION: May 25, 1953. Default decree of condemnation and destruction.

MISCELLANEOUS FOOD

20700. Misbranding of Lemon Quick. U. S. v. 113 Cases * * *. (F. D. C. No. 34161. Sample No. 54831-L.)

LIBEL FILED: November 21, 1952, Northern District of Indiana.

ALLEGED SHIPMENT: On or about July 21, 1952, by the J-A Corp., from Chicago, Ill.

PRODUCT: 113 cases, each containing 24 3-ounce bottles, of Lemon Quick at South Bend, Ind.

Examination showed that the article was essentially an artificially colored mixture of citric acid and dextrose, with small quantities of dried lemon juice, lemon oil, calcium phosphate, egg white, and ascorbic acid in imitation of dried lemon juice.

NATURE OF CHARGE: Misbranding, Section 403 (a), the vignette on the label depicting a portion of a lemon with what appeared to be a drop of lemon juice and the following statements in the labeling of the article were false and misleading since they represented and suggested that the article was dried lemon juice, whereas such was not the fact: (Label) "Lemon Quick * * * Powdered Lemon Concentrate Equals the juice of 27 lemons * * * Use exactly as squeezed lemon juice * * * Use for * * * lemonade * * * lemon sauce, lemon ice cream, lemon sherbet, lemon jello * * * To Make Lemon Juice Mix * * * For Delicious Lemonade" and (display card) "Equals the juice of 27 lemons * * * For every Lemon Use!" and "Use exactly as squeezed Lemon Juice."

Further misbranding, Section 403 (c), the article was an imitation of another food, dried lemon juice, and its label failed to bear in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated; and, Section 403 (f), the information required by